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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,828	11/14/2003	Kamil Paruch	OC01574	2588

24265 7590 10/12/2005

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
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EXAMINER

BERNHARDT, EMILY B

ART UNIT PAPER NUMBER

1624

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/713,828

Applicant(s)

PARUCH ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.  
4a) Of the above claim(s) 18-30 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17, 31 and 37 is/are rejected.
- 7) ☒ Claim(s) 33-36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/6/04 & 8/16/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-17,31,33-37, drawn to compounds, simple compositions where  $X=N$ , classified in class 544, subclass 360; class 514 subclass 253.01.
- II. Claims 1,3-16,31 and 37, drawn to compounds, simple compositions where  $X=CH$ , classified in class 546, subclasses 188,190; class 514 subclass 316.
- III. Claims 18-20, drawn to multiple uses employing compounds of I, classified in class 514, subclass 253.01.
- IV. Claims 18-20, drawn to multiple uses employing compounds of II, classified in class 514, subclass 316.
- V. Claims 21-30 and 32, drawn to complex compositions employing compounds of I/II and additional active ingredients for various uses, classified in class 514, subclasses various as determined by the nature of coingredients employed.

If Group III or IV elected applicants must a single use. If any of I-IV elected applicants must pick a single species. If Group V is elected applicants

must pick a compound group and an ultimate species pair of ingredients for a specific use.

The inventions are distinct, each from the other because of the following reasons: Groups I and II are drawn to structurally dissimilar compounds as X varies along with R1 and R2 such that they are separately classified, require separate literature searches. Art which may render or anticipate compounds of one group would not necessarily do the same for the remaining in view of the structural dissimilarity of I vs II as a whole.

Group V is independent and distinct from I and II since the simple compositions may be old or obvious for the same or other uses taught by the prior art while the complex combination of ingredients in V may be patentable due to superior or new properties (synergistic effects) not present in the single, active ingredient of I or II. Within group V there is more than one invention as the claims recite multiple combinations which require independent searches and separate consideration for compliance with 35 USC 112.

Inventions I/II and III/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product (MPEP 806.05(h)). In the instant case more than one use is being claimed as evident from the many recited in claim 18.

During a telephone conversation with Mr. Kalanaraman on 9/21/05 a provisional election was made with right of traverse to prosecute the invention of I and in particular species of eg.35, claims 1-17,31,33-37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-30 and 32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be**

entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The abstract of the disclosure is objected to because it does not convey the structural makeup of applicants' compounds. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: The status of the US provisional case is extraneous and should be deleted. Note MPEP 1302.04.

Appropriate correction is required.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 37 requires “purified” compounds but the extent of purity level being covered is not clear. 90%, 95%, 99% pure or some other numerical amount or range is possible but specification provides no guidance as to what degree of purity applicants intend to cover by these claims.

Claims 1-17,31,33-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1. “Isomer” appearing in claim 17 is not adequately enabled. The term reads on all such compounds of the **same weight and formula** regardless of complexity and dissimilarity to what is positively recited for which there is no sufficient enabling disclosure by way of examples or starting material sources how to make much less use.

2. "Heteroaryl", "heterocyclyl" in the claims as well as the plethora of functional groups permitted at various locations in the claims are not adequately enabled.

The specification describes rings that have as many as 14 atoms in any array, both fused and unfused, which can be present at almost every available position in formula I and have a multitude of substituents. Applicants provide no assurance that such a class of derivatives will have the minimum activity needed to practice the invention and there is no basis in the prior art drawn to similar compounds.

Applicants' range reported on p.39 of the specification shows as much as a 10,000 fold variation for compounds much closer in structure to themselves than to remaining claimed genus. Said compounds are all bis-phenylmethyl derivatives at R1/R2 with substitution (when present) with groups such as alkyl, halo, CF<sub>3</sub> and trifluoromethoxy. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Thus, the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a), August 2000 edition has been not met given the breadth of the claims, the level of unpredictability in the art (very structure-sensitive) and the lack of direction (i.e. working examples) provided as to what other compounds might work as inhibitors of 17 $\beta$ -hydroxysteroid dehydrogenase.




Claims 33-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Nothing relevant was found by the examiner from a search in the pertinent art area. Was the proviso appearing in the R3 choice necessitated by prior art?

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

  
Emily Bernhardt  
Primary Examiner  
Art Unit 1624